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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,376	03/24/2000	Kari Alitalo	28967-34140A	2155

7590 09/30/2002

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[REDACTED] EXAMINER

O HARA, EILEEN B

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1646

DATE MAILED: 09/30/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/534,376	ALITALO ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Eileen B. O'Hara	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 July 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5,7-9,11-37 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5,7-9,11-37 and 40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION**

1. Claims 1-5, 7-9, 11-37 and 40 are pending in the instant application. Claims 5, 19, 28, 33 and 37 have been amended, claims 6, 10, 38 and 39 have been canceled and claim 40 has been added as requested by Applicant in Paper Number 11, filed July 1, 2002.

***Response to Amendment***

***Restriction Requirement***

2. Applicants' arguments pertaining to the restriction of the subgroups comprising portions of SEQ ID NO: 8 on pages 6-7 of the amendment have been considered and are persuasive. Therefore, previously withdrawn claims 2, 15-18, 21, 22 and 24-37 have been rejoined and will be examined on the merits.

All pending claims are currently under examination.

***Priority***

3. Applicants' amendment to the specification to recite the priority claimed in the declaration is acknowledged.

***Specification***

4. The disclosure is objected to because of the following informalities:  
Amendment of the specification to recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line is required. Also, the address of the ATCC has been changed. The correct address is:

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American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

Correction is required on pages 44 and 111.

***Withdrawn Rejections and Objections***

5. All rejections and objections of claims are withdrawn in view of Applicants' amendment, with the exception of the rejection maintained below under 112 § 1.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-9, 11-37 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-13 of U.S. Patent No. 6,361,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because in both the application and patent the claims are drawn to methods of promoting endothelial cell growth comprising contacting cells or administering to a patient a

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polypeptide comprising the amino acid sequence of SEQ ID NO: 8 and variants thereof having amino and/or carboxyl terminal truncations and specific amino acid deletions or replacements.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7.1 Claims 5, 7-9 and 11-14 remain rejected and newly rejoined claims 15-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a method of treatment of a patient by identifying a patient in need of modulation of Flt4 activity, for reasons of record in the previous Office Action, Paper No. 9, at pages 8-9, and below.

Applicants' traverse the rejection on pages 8-9 of the amendment and assert that the first step of the claim is not the treatment per se, but rather a step of selecting whom to treat, and that the step of "identifying a patient in need of modulation of Flt4 activity" should not be read in isolation as the treatment per se, but rather, should be read as the identification of whom should receive the VEGF-C treatment, and that because the claim is directed to subject matter that the Examiner concedes to be enables, the rejection should be withdrawn.

Applicants' arguments have been fully considered but are not deemed persuasive. As claim 5 is written, it is a requirement that a patient be identified that is in need of modulation of Flt4 activity for the method to be complete. Because claim 5 is a two step method claim, both steps require that the specification provide support for both parts, and the specification has not

provided support or guidance as how to determine what patient would be in need of modulation of Flt4.

7.2 Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants referral to the deposit of Plasmid FLT-4 on page 111 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State.

7.3 Claims 19-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of stimulating endothelial cell growth comprising administering a polypeptide comprising the amino acid sequence of SEQ ID NO: 8 and variants thereof, does not reasonably provide enablement for gene therapy using nucleic acids encoding these polypeptide fragments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

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commensurate in scope with these claims. The claims as written encompass gene therapy. The instant application provides the results of several experiments that demonstrate that polypeptide fragments of VEGF-C (SEQ ID NO: 8) retain the ability to bind to and activate Flt4 receptor and can stimulate endothelial cell growth. However, claim 27 is drawn to, and the specification has not provided the support and guidance necessary to enable a method of gene therapy. There are no conditions disclosed to be treated, and the specification and prior art have not provided adequate guidance as to the vectors, promoters, transcriptional elements, and administration methods, for example, which are necessary for this type of therapy, and the specification does not provide any working examples. The level of skill in the art of gene therapy is low, and there have been very few successful gene therapy treatments. Thus, the specification fails to teach the skilled artisan how to use the claimed invention without resorting to undue experimentation. The specification has not provided the person of ordinary skill in the art the guidance necessary to be able to perform gene therapy using nucleic acids encoding polypeptide fragments of VEGF-C.

Due to the large quantity of experimentation necessary, the lack of direction/guidance presented in the specification regarding same and the absence of working examples, and lack of success in the prior art, undue experimentation would be required of the skilled artisan to use the claimed invention.

It is believed that all pertinent arguments have been answered.

***Conclusion***

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

LORRAINE SPECTOR  
PRIMARY EXAMINER